

SPL Data Standards Update

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Overview

- SPL Medication Guide Issues – Data Standards Perspective
- SPL (XML) for Blanket No Changes Certification for Product Listing
- SPL (XML) for Salvaged Animal Drug Lot Numbers
- SPL (XML) Reserved NDCs
- Deprecation of use of “drug for further processing” marketing category for “Bulk Ingredient” SPL Document Type
- Validation of the active ingredient and route of administration SPL data elements in SPL files with information for human OTC products approved under an ANDA or NDA.

Separate Section for SPL MedGuide Content

- [Guidance for Industry: SPL Standard for Content of Labeling Technical Questions and Answers \(Draft\)](#)
- **23. Should I submit patient package inserts (PPIs) and Medication Guides (MGs) in SPL?**

Approved patient labeling documents should be included at the end of the SPL file. There are specific Logical Observation Identifiers Names and Codes (LOINC) codes for PPIs and MGs. Use the appropriate LOINC code for identifying this information. Each PPI or MG should have a separate LOINC code.

Direct DailyMed Link to Content from SPL Med Guide Section

- Prominent location & direct access to just the content from the SPL medication guide section

DRUG LABEL INFORMATION

Updated May 18, 2017

If you are a consumer or patient please visit [this version](#).

DOWNLOAD DRUG LABEL INFO: [PDF](#) | [XML](#) 

MEDICATION GUIDE: [HTML](#) 

Running Text

Medication Guide for Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (See the end of this Medication Guide for a list of prescription NSAID medicines.) What is the most important information I should know about medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)? NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases with longer use of NSAID medicines in people who have heart disease. NSAID medicines should never be used right before or after a heart surgery called a "coronary artery bypass graft (CABG)." NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding can happen without warning symptoms and may cause death. The chance of a person getting an ulcer or bleeding increases with taking medicines called "corticosteroids" and "anticoagulants" longer use, smoking, drinking alcohol, older age, having poor health. NSAID medicines should only be used exactly as prescribed at the lowest dose possible for your treatment for the shortest time needed. What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)? NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as: different types of arthritis, menstrual cramps and other types of short-term pain. Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)? Do not take an NSAID medicine if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine for pain right before or after heart bypass surgery. Tell your healthcare provider about all your medical conditions, about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. Keep a list of your medicines to show to your healthcare provider and pharmacist if you are pregnant. NSAID medicines should not be used by pregnant women late in their pregnancy, if you are breastfeeding. Talk to your doctor. What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)? Serious side effects include: Other side effects include: heart attack, stomach pain, stroke, constipation, high blood pressure, diarrhea, heart failure from body swelling (fluid retention), gas, kidney problems including kidney failure, heartburn, bleeding and ulcers in the stomach and intestine, nausea, low red blood cells (anemia), vomiting, life-threatening skin reactions, life-threatening allergic reactions. Continued on reverse side. Continued. Serious side effects include: Other side effects include: liver problems including liver failure, dizziness, asthma attacks in people who have asthma. Get emergency help right away if you have any of the following symptoms: shortness of breath or trouble breathing, slurred speech, chest pain, swelling of the face, weakness in one part or side of your body, or throat. Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms: nausea, there is blood in your bowel movement or it is black and sticky like tar, more tired or weaker than usual, itching, unusual weight gain, your skin or eyes look yellow, skin rash or blisters with fever, stomach pain, swelling of the arms and legs, hands and feet, flu-like symptoms, vomit blood. These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. Other information about Non-Steroidal Anti-

Bullet Formatting Issues

- List type (ordered/unordered) combinations:

This condition can be life threatening. The symptoms may include:

- chest pain
- fast or slow heartbeat
- shortness of breath
- dizziness or fainting

3. **Serotonin Syndrome. This condition can be life-threatening and may include:**

- agitation, hallucinations, coma or other changes in mental status
- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

4. **Severe allergic reactions:**

- trouble breathing
- swelling of the face, tongue, eyes or mouth
- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

Out of Date SPL Medication Guides Repackagers/Relabelers

- Automated notification of updates to SPL files
 - DailyMed RSS Feed

The screenshot shows the DailyMed website interface. At the top, the DailyMed logo is on the left, and navigation links for "ALL DRUGS", "HUMAN DRUGS", "ANIMAL DRUGS", and "MORE WAYS TO SEARCH" are on the right. Below these is a search bar with the placeholder text "Enter drug, NDC code, drug class, or Set ID". A blue bar contains "ADVANCED SEARCH" and "VIEW MORE" buttons. The main content area is titled "NEWS: RSS Updates" with an RSS icon. It includes links to "TO RECEIVE ALL DAILYMED UPDATES FOR THE LAST SEVEN DAYS..." and "TO RECEIVE RSS FEED FOR A SPECIFIC DRUG LABEL...". The first link provides the URL <https://dailymed.nlm.nih.gov/dailymed/rss.cfm>. The second link instructs users to use search tools to find a specific drug label and select "Get Label RSS Feed for this Drug" from the "More Info for this Drug" menu. Social media sharing icons for print, email, Facebook, and Twitter are also present.

ALL DRUGS | **HUMAN DRUGS** | **ANIMAL DRUGS** | **MORE WAYS TO SEARCH** ▼

Enter drug, NDC code, drug class, or Set ID

ADVANCED SEARCH | **VIEW MORE**

NEWS: RSS Updates

TO RECEIVE ALL DAILYMED UPDATES FOR THE LAST SEVEN DAYS...
Copy the URL below and paste it into your RSS Reader application.
<https://dailymed.nlm.nih.gov/dailymed/rss.cfm>

TO RECEIVE RSS FEED FOR A SPECIFIC DRUG LABEL...
Use the search tools to find the specific drug label. Select "Get Label RSS Feed for this Drug" from the menu "More Info for this Drug".

Missing Medication Guide Content in SPL Files



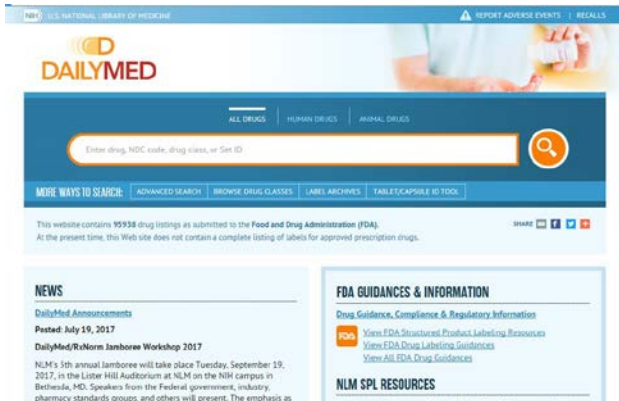
New Improved Medication Guide Section Validation File for Incoming SPL Files

List of Currently Posted SPL Files w/Missing Medication Guide Section

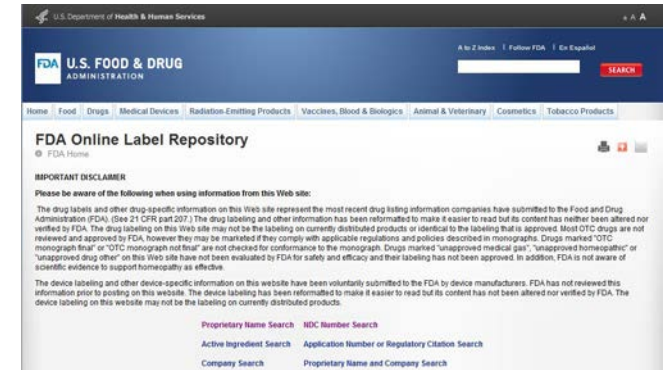
- Posted on FDA SPL web page in XML and Excel Format
- Report of SPL files with missing content of medication sections in SPL files

SPL Dissemination

Correct One File – Update These Sites



DailyMed



Labels.fda.gov



openFDA

Blanket No Changes Certification for Product Listing SPL (XML)

- New SPL document type
 - LOINC Name: “Blanket No Changes Certification for Product Listing”
 - LOINC code: 86445-4
 - *SPL Implementation Guide & Validation Procedures publication in near future*

Salvaged Animal Drug SPL (XML)

- Lot Number

- Existing animal drug SPL document types
- Reuse final lot number SPL data element from “Lot Distribution Data” SPL files
- Business operation
 - NCI Concept Code Name: Salvage
 - NCI Concept Code: C70827
- *Human drug/biological product XML pending completion*
- *SPL Implementation Guide & Validation Procedures publication in near future*

Reserved NDC SPL (XML)

- SPL data element:
 - Health Level Seven code “New”
 - SPL stylesheet view: “Reserved”
- *SPL Implementation Guide & Validation Procedures publication in near future*

Drug for Further Processing Marketing Category in Bulk Ingredient SPL

- Over a year, “drug for further processing” marketing category has been used in “Bulk Ingredient” SPL document type after addition of “Drug for Further Processing” SPL document type.
- Time has been allotted for transition
- *SPL Implementation Guide & Validation Procedures publication in near future*

Validation of Approved Human OTC Drug – Active Ingredient & Route

- Technical validation of the human OTC drug products' SPL documents w/marketing categories of “ANDA” or “NDA.”
 - Active ingredient (UNII)
 - Route of administration
- *SPL Implementation Guide & Validation Procedures publication in near future*

